

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

COPY

IAN WALLACE,

Plaintiff,

vs.

No. 4:18-cv-01859 PLC

PHARMA MEDICA RESEARCH,
INC., TRIS PHARMA INC.;
ROXANE LABORATORIES, INC.;
HIKMA LABS, INC.; and
WEST-WARD COLUMBUS, INC.,

Defendants.

VIDEOTAPED DEPOSITION OF

SHABAZ KHAN, M.D.

Taken on behalf of Plaintiff

November 7, 2019

Reporter: Kimberly A. Harris, CSR

May Reporting Service

Certified Shorthand Reporters
598 Watch Hill Road
Collinsville, Illinois 62234
618-223-8392



1 MR. MUDGE: We are on the record,
2 and the time is approximately 8:54.

3 MR. WENDLER: And for the record,
4 we've all agreed to waive the videographer
5 introduction statement.

6 MS. DREW: Correct.

7 **SHABAZ KHAN, M.D.,**

8 a witness, having been first duly sworn upon oath by
9 the court reporter, testified as follows:

10 [EXAMINATION]

11 QUESTIONS BY MR. WENDLER:

12 Q. Dr. Khan, can you state your full name for
13 us, please?

14 A. **Shabaz Ali Khan.**

15 Q. And where do you live sir?

16 A. **Toronto, it's basically a suburb called**
17 **Stouffville. It's north of Toronto.**

18 Q. And you understand we're here to take your
19 deposition to ask you some questions about the
20 company you work for called Pharma Medica Research --

21 A. **Yes.**

22 Q. -- Inc.; is that correct?

23 A. **Yes.**

24 Q. Is it okay if we just refer to that

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1 company as Pharma Medica for today's purposes?

2 A. **That's perfectly fine.**

3 Q. If you'd be so kind as to tell us what
4 Pharma Medica is, and what it does?

5 A. **Okay. Pharma Medica is a contract**
6 **research organization that does clinical trials for**
7 **pharmaceutical companies. So, basically they give us**
8 **the medication, which would be a generic or a**
9 **reference product. And they do bioavailability**
10 **studies. So we administer the medication to a**
11 **population that is specific to getting that one. It**
12 **could be a general population. It could be a patient**
13 **population, what is required for it based on the type**
14 **of clinical trial it is.**

15 **And then most of our studies are basically**
16 **pharmacokinetic studies, which means that we take the**
17 **blood samples to analyze the concentration of the**
18 **drug in their body.**

19 Q. Okay. And where is Pharma Medica
20 headquartered?

21 A. **Pharma Medica has the headquarters is**
22 **basically at -- in Mississauga in -- That's our**
23 **corporate office, along with our analytical the lab.**

24 Q. Mississauga, where is that?

6

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1 A. **Mississauga is, again, a suburb, just west**
2 **of Toronto.**

3 Q. Okay. In Canada?

4 A. **In Canada, yes.**

5 Q. All right. And I apologize. I should've
6 asked you earlier: Have you ever given a deposition?

7 A. **No, first time. So that's why I was**
8 **seeing how this is all set up.**

9 Q. All right. If at any point in time I ask
10 you a question that you don't understand what I'm
11 asking, just feel free to tell me, and I'll be happy
12 to rephrase it for you. Okay?

13 A. **Sure. Thank you.**

14 Q. Okay. If you want take a break at any
15 time, just let me know, and we'll take a break, as
16 long as there is no questions pending.

17 A. **Definitely.**

18 Q. Okay. Okay. Any questions so far?

19 A. **I tend to nod my head and all instead of**
20 **answering. So just let me know to speak up the**
21 **answer.**

22 Q. She'll hit you, if you do that.

23 A. **All right.**

24 (Whereupon, an off the

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1 record discussion was
2 held, which by direction
3 was not stenographically
4 reported.)

5 Q. (BY MR. WENDLER) Okay. Did you do
6 anything, Dr. Khan, to prepare for the deposition
7 today? Did you read anything?

8 A. **I reviewed some of the pictures, and the**
9 **videos, and briefly look at the -- over-viewed the**
10 **SAE report.**

11 Q. Reviewed the what?

12 A. **The SAERs, serious adverse event report.**

13 Q. Anything else?

14 A. **No. The general SOPs, and procedures, and**
15 **all the stuff is there; right?**

16 Q. All right. You also attended, I believe
17 by telephone, the deposition of my client,
18 Mr. Wallace; is that correct?

19 A. **No.**

20 Q. You did not?

21 A. **Only Dr. Jordan.**

22 Q. You attended the deposition of Dr. Jordan
23 by telephone; correct?

24 A. **Correct.**

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1 **A. In India, yes.**
2 **Q.** All right. And you said you practiced in
3 India as a licensed medical doctor for how long, one
4 year?
5 **A. Approximately a year.**
6 **Q.** All right. And during that one year, did
7 you draw blood from patients?
8 **A. Yes. Basically doctors do not do much.**
9 **But yes, we do draw blood and all. There is cases**
10 **say where some of the patients request us to do it,**
11 **and we do it. We do it.**
12 **Q.** Did you say doctors do not do much?
13 **A. Not for the blood draws. It's basically**
14 **it's the nurses. In India it's the nurses. In**
15 **Canada and all it's the technicians who come and do**
16 **it. In India it's basically nurses.**
17 **Q.** All right.
18 **A. But doctors, yeah, especially when we are**
19 **interns, we do a lot so that we get the experience of**
20 **what arterials need to be drawn, what tests need to**
21 **be ordered, and we -- The nurses tend to order --**
22 **Like you need to attend to the patients; right? You**
23 **need to be with them. And definitely they'll**
24 **appreciate when you yourself are attending to them a**

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1 **lot more.**
2 **Q.** Well, how old were you when you came to
3 Canada?
4 **A. You ask. It's been back so far. So I**
5 **came in 2003. So I will be -- '76, '75 born, so**
6 **five. Around 28.**
7 **Q.** Twenty-eight? All right. Back to Pharma
8 Medica --
9 **A. Twenty-seven, 28.**
10 **Q.** What is your title at Pharma Medica?
11 **A. Vice-president clinical operations.**
12 **Q.** Vice-president clinical operations?
13 **A. Yeah.**
14 **Q.** And what does that entail? What are your
15 job duties there?
16 **A. So basically I look after our clinic**
17 **location. There are two locations in Canada. We**
18 **have a clinic location, and then we have the head**
19 **office, or the corporate location.**
20 **The clinic location basically deals with**
21 **all the clinical activities where we have subjects or**
22 **volunteers who come to participate in the study. So**
23 **we have a screening department. We have a recruiting**
24 **department. We have the clinics where the subjects**

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1 **come and stay. And then the supporting departments**
2 **along with them, like the kitchen, the admin people,**
3 **the facilities and all. So all of these activities**
4 **take place at the clinic.**
5 **So all the departments in the clinic,**
6 **basically I oversee all the functions, which includes**
7 **the clinic staff, technicians, the group leader, the**
8 **study coordinators, the screening department, which**
9 **is again the technicians, screening coordinators,**
10 **managers, recruiters, and the kitchen staff, and**
11 **cleaning and all.**
12 **Q.** All right. And this case is about what
13 transpired at Pharma Medica's St. Charles, Missouri
14 clinic. You're aware of that; right?
15 **A. Yes, sir.**
16 **Q.** Were you in charge of that at the time
17 these studies were initiated?
18 **A. So basically I used to oversee both the**
19 **sites. However, in 2015, mid 'til almost 2017, I was**
20 **more based in Canada. I had a senior director who**
21 **was over here at this site, Louis Co. He used to**
22 **oversee the clinical activities.**
23 **Q.** And who was that?
24 **A. Louis Co.**

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1 **Q.** Louis Co?
2 **A. Yeah. Yes.**
3 **Q.** And he's no longer with Pharma Medica; is
4 he?
5 **A. No. No. No, he's not.**
6 **Q.** All right. Do you know, sir, was the St.
7 Charles Pharma Medica clinical operations governed by
8 the same policies and procedures as the Canadian
9 Pharma Medica clinic?
10 **A. They were very, very identical.**
11 **Q.** Okay.
12 **A. But there are some procedures which are**
13 **slightly different because of the local laws from**
14 **Missouri, and the U.S. and all. Not much in regards**
15 **to the clinical activities, but more like the human**
16 **resources policies, and the narcotics, and all of**
17 **that stuff.**
18 **Like, for example, in the U.S. or**
19 **Missouri, you can have the narcotics in the pharmacy,**
20 **and then you have the licenses for Schedule I, II,**
21 **and III.**
22 **In Canada it's totally different. It's a**
23 **qualified person in charge who keeps it separately**
24 **and manages it. So those are the slight differences.**

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1 Q. Okay. The slight differences that you're
2 talking about between the Canadian Pharma Medica
3 clinic and the St. Charles, Missouri clinic, would
4 you agree they have nothing to do with what this
5 lawsuit's about, the differences?

6 A. Yeah, I agree.

7 Q. You agree?

8 A. They should be very, very similar.

9 Q. All right. My client's Mr. Ian Wallace.
10 Did you ever meet him, or ever talk to him?

11 A. I can say yes, I have met him. Maybe
12 during the studies, prior to the 4109 and 3952,
13 before that, talked to him; could've spoken to him
14 about any of the study issues.

15 Like I do a lot of procedures on the side
16 myself, too, like asking questions, consent, and
17 these things and all. So in the course of the study,
18 yes, I would have spoken.

19 Q. All right. Let me ask you this: Do you
20 have an independent recollection of Mr. Wallace? If
21 he walked in the door today, would you know him?

22 A. Yes, I think I should be able to.

23 Q. Okay. Do you have an independent
24 recollection of anything Mr. Wallace said to you, or

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1 to anyone else --

2 A. No.

3 Q. -- that you heard?

4 A. No, I can't.

5 Q. Do you have an independent recollection of
6 anything you said to Mr. Wallace?

7 A. No.

8 Q. All right. And back to Pharma Medica, who
9 else --

10 Strike that.

11 Are you a part owner of Pharma Medica?

12 A. No.

13 Q. Okay. You are just an employee?

14 A. Yes.

15 Q. Are you an officer or director of Pharma
16 Medica?

17 A. I'm the vice-president. So --

18 Q. So, yes, you are?

19 A. Okay.

20 Q. All right. Who actually owns Pharma
21 Medica? I realize it's a corporation. But who are
22 the shareholders?

23 A. I know our president and CEO, Latifa
24 Yamlahi, and Mohammed Bouhajib, who is also VP of

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1 biomedical lab. Then Mike Panahi. I think he's a
2 silent partner.

3 Q. And they all reside in Canada?

4 A. Yes.

5 Q. You don't have a U.S. medical degree;
6 correct?

7 A. Correct.

8 Q. Do any of the Pharma Medica owners have a
9 U.S. medical degree?

10 A. No, I don't think so. I don't know.

11 Q. All right. So you were telling us earlier
12 with the business Pharma Medica is, and correct me if
13 I'm wrong, but Pharma Medica works on a contract
14 basis with pharmaceutical companies to test and
15 gather data for testing pharmaceuticals that the
16 pharmaceutical companies want to try to market at
17 some point. Is that a fair summary?

18 A. They do a comparative bioavailability
19 study, which shows that the generic and the reference
20 product -- The reference product's already marketed
21 and approved by a similar --

22 Q. I'm sorry. Can you repeat?

23 A. So we do a bioavailability comparative
24 studies. So where you compare a generic one, a drug

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1 product, with a reference product, which is already
2 approved and marketed.

3 Q. Okay.

4 A. In that way.

5 Q. All right. So, if you take a
6 pharmaceutical drug that's already on the market with
7 a brand name, your company does the testing of the
8 generic equivalent?

9 A. Both of them.

10 Q. Both?

11 A. So, we don't do any placebo trials. So,
12 when we have a population of subjects, for example,
13 in 4109 they were receiving a drug product, which is
14 a test product, the one that is generic, and they are
15 receiving the other one that's a reference product
16 already in the market. So half of them will get the
17 test. Half of them will get the reference. And in
18 the next period, they will switch over. This is a
19 standard bioavailability comparative studies. Some
20 of them could be parallel, which they only get half
21 and half.

22 But where we compare over here the
23 concentration level of the drug are similar or not to
24 the ones in the reference one.

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1 Roxane Laboratories product; correct?
 2 **A. Correct.**
 3 **Q.** Did you have any hand in drafting this?
 4 What do you call this, a protocol, or a contract?
 5 What do you call this?
 6 **A. This one is the protocol. This is the**
 7 **study protocol that we conduct the study accordingly**
 8 **with. Now --**
 9 **Q.** Did you have any hand in drafting this
 10 document, Exhibit No. 1?
 11 **A. I would say no.**
 12 **Q.** Who drafted it, do you know?
 13 **A. So, basically --**
 14 MR. MCBREARTY: Off the record.
 15 (Whereupon, an off the
 16 record discussion was
 17 held, which by direction
 18 was not stenographically
 19 reported.)
 20 **A. So basically the drafting of the protocol**
 21 **is -- comes in from what the sponsor wants, sponsor**
 22 **requirements, along with our scientific affairs team.**
 23 **Q.** (BY MR. WENDLER) Your sign what?
 24 **A. Scientific affairs team at the corporate**

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1 **location. They review --**
 2 **Q.** I'm still not understanding. Your signed
 3 what?
 4 **A. Scientific affairs.**
 5 **Q.** Scientific affairs?
 6 **A. The department over there.**
 7 **Q.** All right.
 8 **A. They look at that, what are the guidelines**
 9 **of the recommendations for conducting trials. What**
 10 **are the requirements, age, sample collection, what**
 11 **time should it be taken, along with the principal**
 12 **investigator. They all review it together, and draft**
 13 **it. I do look at most of the protocols. I don't**
 14 **think I did this one, because this one was the one**
 15 **that we had done quite a few times, in order to**
 16 **looking at the feasibility, and the logistics of the**
 17 **studies.**
 18 (Whereupon, Plaintiff's
 19 Exhibit No. 2 was marked
 20 for identification by Mr.
 21 Wendler.)
 22 **Q.** (BY MR. WENDLER) Okay. Let me hand you
 23 Exhibit No. 2. And this is the protocol for the
 24 study for the --

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1 **A. Pseudo --**
 2 **Q.** -- protocol 3952, bearing Bates number
 3 168.
 4 MR. MCBREARTY: Thank you.
 5 **Q.** (BY MR. WENDLER) Are you familiar with
 6 Exhibit No. 2?
 7 **A. Yeah. I had reviewed this protocol**
 8 **earlier. I'd gone through it.**
 9 **Q.** Okay. All right. And with regard to
 10 Exhibit No. 2, that's the study --
 11 **A. 3952.**
 12 **Q.** -- for the Tris Pharma --
 13 **A. Correct.**
 14 **Q.** -- study; correct?
 15 **A. Yes.**
 16 **Q.** All right. Did you have a hand in
 17 drafting, or participating in the drafting of the
 18 Exhibit No. 2, the Tris Pharma protocol?
 19 **A. No, I don't think so. Not that I can**
 20 **remember.**
 21 **Q.** I want to ask you some questions about
 22 both of these studies combined. And rather than ask
 23 the same questions over and over, I'm going to ask
 24 you about these Exhibits in the singular rather than

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1 the plural. Okay?
 2 **A. Okay.**
 3 **Q.** But the same questions will be applicable
 4 to both studies.
 5 Okay. First, the guidelines that are
 6 created for these, for the study, who creates those
 7 guidelines?
 8 **A. So, basically the scientific affair team,**
 9 **along with our protocol writing team.**
 10 **Q.** The scientific affair team at Pharma
 11 Medica?
 12 **A. Yeah. They review the F.D.A. guidelines.**
 13 **Q.** Okay.
 14 **A. What is there previously, if F.D.A. had**
 15 **issued any guidelines on conduct of these studies and**
 16 **all. They'll review those guidelines, along with the**
 17 **-- consultation with the sponsors.**
 18 **Q.** The sponsor? And in this case, the
 19 sponsor for Exhibit No. 1 would be --
 20 **A. Is Roxane.**
 21 **Q.** -- Roxane Laboratories; correct?
 22 **A. Yes.**
 23 **Q.** And the sponsor for Exhibit No. 2 protocol
 24 study would've been Tris --

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1 **A. Tris.**
2 **Q.** -- Pharma; correct?
3 **A. Yes.**
4 **Q.** All right. The sponsor, you said, has
5 some input in creating the guidelines; correct?
6 **A. Not the guidelines. Guidelines are**
7 **provided by the F.D.A.**
8 **Q.** All right.
9 **A. All right. Any other studies specific**
10 **design and all, the sponsor will have an input. It's**
11 **their study.**
12 **Q.** For example, what does the sponsor --
13 **A. Well, if the sponsor says that, 'Oh, I**
14 **want to include -- what do you call -- people or**
15 **volunteers over the age of 55 --**
16 **Q.** Okay.
17 **A. -- to 60.' Then our scientific affairs**
18 **team will check and say, 'No. The guidelines state**
19 **that it has to be up to 50 only.'**
20 **Q.** Okay.
21 **A. So we substantiate that, and tell them**
22 **that, 'These are the guidelines. So we are stopping**
23 **at 50.'**
24 **Q.** Okay. So the sponsor can create

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1 specifications, and Pharma will do it, Pharma Medica
2 will do it, provided it's within the F.D.A.
3 guidelines; correct?
4 **A. Within the F.D.A. guidelines, yes.**
5 **Q.** So the sponsor can determine things such
6 as age of the participants; correct?
7 **A. Yes.**
8 **Q.** Okay. And the sponsor can determine when
9 blood is to be drawn?
10 **A. No. I don't think the sponsor can**
11 **determine when the blood is drawn, unless they have**
12 **data with them. If they have done previous trials,**
13 **and which indicates that you need these sampling time**
14 **points and all.**
15 **Q.** Yes.
16 **A. So they can tell us like, 'You know what?**
17 **We have done trials. This is the data we have for**
18 **these time points. This is where we found**
19 **deficiency. And we want to add these time also into**
20 **it, or remove time lines in those specific matters.'**
21 **Q.** By way of example, the sponsor can say,
22 'We want the blood samples to be drawn every hour on
23 the hour.' By way of example; am I right?
24 **A. If they have data supporting that, and if**

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1 **it's in agreement with -- What do you call --**
2 **Q.** F.D.A.?
3 **A. -- F.D.A. guidelines.**
4 **Q.** Okay.
5 **A. Then, yes.**
6 **Q.** All right. And reading through the
7 protocol, it looks like the sponsor also has some
8 input on when the patients are allowed -- are allowed
9 to eat? I said patients. I meant participants.
10 **A. So basically it's not allowance to eat.**
11 **It's, again, F.D.A. guidelines says for the**
12 **bioavailability studies; right?**
13 **Q.** Uh-huh.
14 **A. If it's a fed study, they're evaluating**
15 **concentration of the drug when the drug is taken on a**
16 **full stomach.**
17 **So F.D.A. has specific guidelines.**
18 **Actually, they state how much concentration of**
19 **carbohydrates, fats, and protein should be there.**
20 **They should be taking it within 30 minutes. So there**
21 **are very specific guidelines.**
22 **And also, these guidelines state that for**
23 **the majority of the studies, they have to be fasting**
24 **for at least -- what do you call, four hours.**

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1 **Q.** All right.
2 **A. So the most engaging portion is basically**
3 **the time of the duration that they're fasting before**
4 **and after.**
5 **Q.** Okay.
6 **A. Other than that, it's regular times.**
7 **Q.** Okay. If you could look at Exhibit No. 1,
8 sir, turn to Page 10, Bates number 361. Where it
9 says Table of Contents, do you see that?
10 **A. Yes.**
11 **Q.** All right. And then on Exhibit No. 2 --
12 **A. Uh-huh.**
13 **Q.** -- on Page 15, again we have a Table of
14 Contents. I want to ask you about those.
15 **A. Sure. Page 15?**
16 **Q.** Fifteen, right. It's Bates numbered 0182.
17 **A. Okay.**
18 **Q.** What we're looking at in the Exhibit is
19 Table of Contents for the study protocol; correct?
20 **A. Yes.**
21 **Q.** And who actually created this study
22 protocol? Who printed it out? I see the Pharma
23 Medica logo on the top of the page, but who actually
24 printed this out?

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1 **A. Printed it out, or completed it, how it**
 2 **would be approved, and reviewed, and signed, and then**
 3 **distributed?**

Q. I'll go with your question. It's much
 better.

Who printed it out, created it, and
 approved it?

A. Okay. So, it's different levels again.
We have a separate team called the protocol writers.

Q. Uh-huh.

A. So they are the ones who complete and
draft the protocols. And you will see there is a
page -- Is it after the Table of Contents? Over
here, key personnel and facilities, you'll see there
the name of the protocol writers on it.

Q. Okay. And who is the key personnel
 protocol writer?

A. The protocol writer for this is Erangi.

Q. And is that a Pharma Medica employee?

A. Yes.

Q. What is his name, or can you -- Erangi?
 What's the last name?

A. Tennakoon.

Q. Okay. And again, he works for Pharma

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1 Medica?

A. Yes.

Q. And there's also a person here listed --

A. The vice-president of quality assurance.

Q. Radu?

A. He's the vice-president of scientific
affairs, the department I was telling you, scientific
affairs.

Q. This is on Exhibit No. 2; correct?

A. Yes.

Q. All right. Exhibit No. 1, who were the
 key personnel?

A. The protocol writers was Arun Mehan. The
vice-president of quality assurance was Mary
Stipancic. Vice -- Senior vice-president of
scientific affairs was Dr. Radu Pop. Then again,
vice-president of laboratory operations, Mohammed
Bouhajib. Our clinical trial director, Latifa
Yamlahi. And principal investigator, Dr. Heather
Renee Jordan.

Q. All right. And all of those individuals,
 with the exception of Dr. Jordan --

A. Dr. Jordan.

Q. -- work at Pharma Medica headquarters in

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1 Canada; correct?

A. I think Dr. Radu is retired.

Q. Okay.

A. Okay.

Q. Did he work at --

A. He worked --

Q. -- Pharma?

A. -- at headquarters, yes.

Q. Okay. Now, the document that we have in
 front of us, with regard to the Table of Contents, it
 appears that this document gives parameters, and
 instructions, and definitions on a whole bunch of key
 areas. If we look at -- There's a study design
 section. Do you see that?

MS. DREW: Which document? Which
 Exhibit are you using?

MR. WENDLER: It's in both.

MS. DREW: Okay.

Q. (BY MR. WENDLER) Section 8.0 says study
 design.

A. Yes.

Q. Do you see that?

A. Yes.

Q. All right. And then there's a next

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1 paragraph, or next entry below design says interval
 2 between doses.

A. Okay.

Q. So this document regulates the time in
 between doses of the drug that's being tested;
 correct?

A. Correct.

Q. And then was Section 8.7 says study
 population. That's where the geographic
 characteristics --

A. Yeah.

Q. Not geographic.

Strike that.

That's where the demographic
 characteristics of the participants are regulated and
 restricted; correct?

A. Are indicated, yes.

Q. All right. Next Section, 9.0, subject
 selection, talks about general screening, how the
 subjects are to be screened prior to participation or
 entry in the study; correct?

A. Correct.

Q. And there is the screening procedures that
 sets out the procedures that are to be followed for

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1 **setting, we always worked together. But she didn't**
2 **report to me.**

3 **Q.** Okay. When you said you always worked
4 together, is that when you were physically present
5 with each other?

6 **A.** **No. We would always talk, discuss. I**
7 **used to ask a lot of advice from her.**

8 **Q.** Okay.

9 **A.** **And then she would ask me about**
10 **procedures, like, 'Hey, can we do this?' But we**
11 **always were in constant contact.**

12 **Q.** Okay. Do you have any knowledge, Dr.
13 Khan, with regard to why Pharma Medica chose to use
14 needle sticks for blood draws rather than catheters?
15 Do you know why?

16 **A.** **So because catheters -- catheters have --**
17 **F.D.A. does not approve a device that is used on a**
18 **catheter called a mandarin or an obturator.**

19 **Q.** I'm sorry. You said that the F.D.A. does
20 not approve the use of catheters for --

21 **A.** **It approves the use of catheter. But a**
22 **catheter, you cannot leave it open. You have to**
23 **close it; right?**

24 **Q.** Right.

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1 **A.** **So there is a specific device that is used**
2 **in Europe and Canada called as an obturator. So, if**
3 **this is a catheter, you put the obturator in there,**
4 **and you close it. F.D.A. does not approve the use of**
5 **the obturator in U.S.**

6 **Now, the other option for using a catheter**
7 **is to keep on flushing it, introducing either Heparin**
8 **or a saline flush. We are not that particular, and**
9 **it's not recommended for the scientific team to**
10 **always introduce saline flush, and what do you call**
11 **-- to use Heparin flush also, especially when it's**
12 **healthy individuals.**

13 **Q.** All right.

14 **A.** **Okay. So that's the reason why we cannot**
15 **use it. If F.D.A. approves it, we'll use it.**

16 **Q.** Okay.

17 **A.** **Or we would have used it.**

18 **Q.** Is there any prohibition against using
19 catheters for blood draws in studies such as are at
20 issue here?

21 **A.** **There is no prohibition, but because it's**
22 **not F.D.A. allowed, we cannot use it.**

23 **Q.** Well, if it's not F.D.A. allowed --

24 **A.** **The obturator is not approved by F.D.A. to**

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1 **be used on the catheter. That's why we cannot use**
2 **it.**

3 **Q.** But the Heparin flush is allowed?

4 **A.** **I don't think Heparin flush is allowed.**

5 **Q.** Okay. Let me ask you this: Are you aware
6 whether or not catheters are allowed to be used in
7 the U.S. for pharmaceutical studies such as at issue
8 here?

9 **A.** **You can use catheters, provided saline**
10 **flush or the Heparin flush is allowed.**

11 **Q.** All right. And do you know which is more
12 costly, or more expensive to use, the catheters or
13 the needle for blood draws?

14 **A.** **I would say they are both the same.**

15 **Q.** Okay. Do you know specifically why Pharma
16 Medica did not use catheters rather than the needle
17 for blood draws?

18 **A.** **Yeah. Because the obturator and the flush**
19 **were not approved.**

20 **Q.** Not approved by?

21 **A.** **The obturator are not approved to be used**
22 **over here in the U.S. And then we did not have the**
23 **approval to use the flush, saline flush.**

24 **Q.** Did not have approval to use the saline

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1 flush by whom?

2 **A.** **By scientific affairs team, and also with**
3 **the drug. So if the drug concentrations are going to**
4 **be affected by saline flush, no, you cannot use it.**

5 **Q.** Okay. So what you're saying, correct me
6 if I'm wrong, is the scientific affairs and the
7 sponsor did not approve the use of the catheters;
8 correct?

9 **A.** **And the flush.**

10 **Q.** With the flush?

11 **A.** **Yeah.**

12 **Q.** Okay. And scientific affairs is Pharma
13 Medica; correct?

14 **A.** **Correct.**

15 **Q.** All right. So in order to use the
16 catheters, both would have to agree to it? The
17 sponsor would have to agree to it, and the scientific
18 affairs department at Pharma Medica would have to
19 agree to it; correct?

20 **A.** **Yes.**

21 **Q.** All right.

22 **A.** **Now, there are certain studies, certain**
23 **agencies which only strictly ask for catheters to be**
24 **used. For those ones, we would use bags. For these**

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1 **Q.** Okay. You did not tell Dr. Jordan or
2 Louis Co to go to the hospital; am I correct?
3 **A.** **No.**
4 **Q.** Am I correct?
5 **A.** **I did not say that.**
6 **Q.** Okay. Have you seen any of the written
7 reports by Dr. Hull regarding this case?
8 **A.** **No, I did not get a chance to see that.**
9 **Q.** Okay. I'm going to hand you Exhibit No.
10 4, sir.
11 (Whereupon, Plaintiff's
12 Exhibit No. 4 was marked
13 for identification by Mr.
14 Wendler.)
15 **Q.** (BY MR. WENDLER) This is a document that
16 was produced to us by Roxane Laboratories. It says
17 Master Agreement. Are you familiar with that?
18 **A.** **I heard about Master Agreement, but I**
19 **don't go through it with them. It's basically the**
20 **project management team and the sponsor have it.**
21 **Q.** All right. Can you tell me how this
22 Master Agreement is different from, or has --
23 provides different regulations than Exhibit No. 1,
24 the protocol?

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1 **A.** **So this is study specific, how the**
2 **particular study and all is going to be conducted.**
3 **Q.** Exhibit 1 is, the protocol?
4 **A.** **Yes, the protocol.**
5 **Q.** All right.
6 **A.** **Master Agreement, this is the first time**
7 **reading it. I haven't read it ever before.**
8 **Q.** That's fine.
9 **A.** **It's basically -- I think it's the**
10 **understanding with Pharma Medica and the sponsor.**
11 **Q.** So it's your understanding that this
12 Master Agreement that we've marked as Exhibit No. 4
13 provides a different --
14 Strike that.
15 Is it your understanding that the Master
16 Agreement that we have marked as Exhibit No. 4
17 provides additional guidelines that Pharma Medica was
18 to follow in the testing of Roxane Laboratories
19 medications?
20 MS. DREW: Object to the form of the
21 question; calls for speculation. Dr. Khan's already
22 said he's never seen the document before.
23 MR. MCBREARTY: Join.
24 **A.** **Yeah.**

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1 MS. DREW: You can go ahead and see
2 --
3 **A.** **No. I have to read through it, and then**
4 **let you know.**
5 **Q.** (BY MR. WENDLER) Go ahead, and skim
6 through it, if you want, or read through it.
7 **A.** **No. No. I have to read it. It's large.**
8 **Q.** I -- This was just produced to us in
9 discovery.
10 **A.** **Yeah.**
11 **Q.** I'm trying to figure out what it is. I
12 thought you might be able to help me.
13 **A.** **No. Basically I don't get the Master**
14 **Agreements. It's between project management and the**
15 **sponsor. They have it, and they save it.**
16 **Q.** Okay.
17 **A.** **So for us, it's always the protocol that**
18 **dictates the study's specific conduct.**
19 **Q.** All right. You said the Master Agreement
20 is between who?
21 **A.** **The project management team of Pharma**
22 **Medica and the sponsor.**
23 **Q.** And who is the project management team?
24 **A.** **Our director of project management is**

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1 **Marianna Colalillo, and then the other project**
2 **managers who work with her. So there is Amin,**
3 **Maureen. There's Joanna. There is Whitney. There**
4 **is Fareen. Yeah.**
5 **Q.** How many employees does Pharma Medica
6 have?
7 **A.** **Right now in Canada we have approximately**
8 **around 200-plus or so.**
9 **Q.** Did you read through the adverse event
10 reports relative to Mr. Wallace?
11 **A.** **Yes, I had reader earlier the SAERs,**
12 **adverse event report that was generated.**
13 **Q.** All right. Well, let me ask you this:
14 When Mr. Wallace's AST was reported on June 15 at the
15 rate of 59, do you agree that's above the normal
16 range?
17 **A.** **Can I see the report? Because it'll have**
18 **the ranges in there.**
19 **Q.** If I can find it, I'll show it to you.
20 Let's see. Okay. We'll mark this as Exhibit No. 5.
21 MR. MCBREARTY: Which one?
22 MR. WENDLER: Bates number 422. It
23 was Exhibit 4 from the Dr. Jordan deposition.
24 (Whereupon, Plaintiff's

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